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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/775,281	02/01/2001	James L. McMenimen	P-9153.01	8273

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EXAMINER	
JASMIN, LYNDA C	

ART UNIT	PAPER NUMBER
3627	

DATE MAILED: 09/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/775,281	MCMENIMEN ET AL.
	Examiner	Art Unit
	Lynda Jasmin	3627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 7-9 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 7-9 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Amendment received on June 10, 2004 has been acknowledgment. The serial number recorded on this amendment (09/775,262) is incorrect.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 9, the recitation "wherein the inventory status information is provided by medical devices taken from inventory the communicate with manufacturer computer server" renders the claim indefinite, since it appears to be incomplete.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt et al. (5,725,559), in view of Colligan et al. (6,298,443).

Alt et al. discloses a medical device manufacturing and supply information management system (IMD) having a Web-enabled information network with data communications with the manufacturing process and in bi-directional data communications scheme with a programmer [col. 4, line 55; the communication between programmer (40) and manufacturer is via Internet (i.e., web-enabled)], at least one implanted medical device having specific features [via device (10) a programmable implant with features based on the need of a patient], including customized features having customized data sets [via allowing the patient to receive the benefit of improved features or parameters of the device when, if, and as needed by a patient] deployed from a known source [col. 4, lines 50-52; the upgrade data received from the manufacturer via the Internet is "patient specific" in that it requires a specific device serial number, i.e., a unique ID associated with a specific device implanted in a specific patient]. However, Alt et al. fails to explicitly disclose the web-enabled information network being to data communication with shipping/delivery, and manufacturing facility

to start a build-to-order/build-to-replenish operation, and in data communication with shipping/delivery and maintain an inventory.

Colligan et al. discloses the concept of managing inventory and product control having a build-to-order custom-programmed CD ROM that is configured for a specified individual computer system (with Service Tag number of the specified computer system) and constraint to be downloaded to and operable on only the specified individual computer system. Colligan et al. also discloses a software transport package manufacturing process (300) to retrieve customer order record by part number and a shipping method. Colligan et al. further discloses the concept of maintain and inventory via an asset tag (col. 11, lines 24 and 25).

From this teaching of Colligan et al., it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modify the upgradable implanted medical device of Alt et al. to include the customized order fulfillment taught by Colligan et al. in order to fit customer's specific needs.

Response to Arguments

7. Applicant's arguments filed June 10, 2004 have been fully considered but they are not persuasive.

8. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the use of a programmer to reprogram an already implanted medical device) are not recited in the rejected claim(s). Although the claims are interpreted in light of the

specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

9. Applicant next argues that Colligan does not address the manufacture of medical device an inventory control for the same. It is the Examiner's position that Colligan discloses an asset tag that is useful for identifying and inventory of computer systems for accounting purposes and the like. Further, the Examiner maintains that the fact the ordered/replenish product is an implantable device does not materially affect the method of fulfilling customized orders. Therefore, Colligan et al. discloses receiving customized orders via computer and making component selections based on the received orders, regardless of the specific device ordered (i.e., the methodology for receiving customized orders via computer and making component selections from an inventory database based on the ordered product will be the same regardless of that is ordered – it is just that the specific components selected will vary depending on what was ordered; the steps for fulfilling the order will be the same).

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Clynch discloses a method of producing custom fit medical devices.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynda Jasmin whose telephone number is (703) 305-0465. The examiner can normally be reached on Monday- Friday (8:00-5:30) alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert P Olszewski can be reached on (703) 308-5183. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lynda Jasmin 9/20/04
Primary Examiner
Art Unit 3627

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